DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 27, 2015

Hivox Biotek, Inc.
Clytie Chiou
Product Manager
5 F., NO. 123, Shingde Road, San-Chong District
New Taipei City 24158, Taiwan

Re: K143737
Trade/Device Name: EM25-glute toning device
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June 24, 2015
Received: June 26, 2015

Dear Clytie Chiou,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143737

Device Name

EM25 - glute toning device

Indications for Use *(Describe)*

The EM25 - glute toning device is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrodes for the purpose of improvement of muscle tone of the buttocks muscles.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

5.1 Type of Submission: Traditional

5.2 Preparation Date: July 22, 2015

5.3 Submitter:

Address:	Hivox Biotek, Inc. 5F., No. 123, Shingde Road, San-Chong District, New Taipei City 24158, Taiwan (R.O.C.)
Phone:	+886-2-8511-2668
Fax:	+886-2-8511-2669
Contact:	Clytie Chiou (clytie.chiou@hivox-biotek.com)
Registration number:	9611558

5.4 Identification of the Device:

Proprietary/ Trade name:	EM25 - glute toning device
Classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Device Classification:	II
Regulation Number:	890.5850
Panel:	Physical Medicine
Product Code:	NGX

5.5 Identification of the Predicate Device:

Predicate Device Name:	Buttock Muscle Stimulator, model: WL-2413E
Manufacturer:	Well-Life Healthcare Limited.
Regulation number:	890.5850
Product Code:	NGX
510(k) Number:	K123075

5.6 Intended Use and Indications for Use of the subject device.

The EM25 - glute toning device is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrodes for the purpose of improvement of muscle tone of the buttocks muscles.

5.7 Device Description

The proposed device, EM25 - glute toning device is a self-adhesive EMS device for muscle training. The device can be applied with accuracy thanks to the use of EMS technology. Made from medical-quality silicone rubber, the elegantly designed EMS pad is extremely slim and flexible and adapts perfectly to the area to be treated. The high-tech circuit provides energy-efficient treatments of 20 minutes each.

Electrical muscle stimulation (EMS) is a widespread and generally recognized method and has been used in sports medicine and rehabilitation for years. In sports and fitness, EMS is used to complement conventional muscle training, to increase the performance of muscle groups and to adjust physical proportions to achieve the desired aesthetic results.

EMS devices work by passing electrical currents over the skin. The gel pad is used as a transfer medium and is subject to natural wear and tear. The gel pad must be replaced if it stops providing sufficient contact, as this will prevent the EMS pad from sticking to the skin. If it is not replaced, the partially increased current density could irritate the skin.

The proposed device, EM25 - glute toning device is assembled with the PCBA and electrode, and the LR03 (AAA) battery supplies the safe low-frequency current. The electrode stuck on the human skin purposes to train the deep muscle. There are 0-15 intensity levels for EM25 - glute toning device. The maximum voltage is divided by 15 (levels) and accumulated for each voltage. But the each increased amperage cannot be over 2%. The intensity level will be minimum when turning on. The user can adjust it from 0 to 15 and gradually increase the intensity level. The whole treatment time is 20 minutes, and then the device switches off automatically.

5.8 Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the EM25 - glute toning device.

Testing Item	Standard and regulations applied
Biocompatibility	ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process.
	EN ISO 10993-2:2006, Biological evaluation of medical devices – Part 2: Animal welfare requirements.
	EN ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro Cytotoxicity.
	EN ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
	EN ISO 10993-12:2009, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.
Software	IEC 62304: 2006 Medical device software - Software life cycle processes.
	ISO 14971:2007 Medical devices - Application of risk management to medical devices.
Electromagnetic Compatibility & Electrical Safety	IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
	IEC 60601-1-11, Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment.
	IEC 60601-2-10, Medical Electrical Equipment - Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators.
Risk Management	ISO 14971:2007 Medical devices - Application of risk management to medical devices.

All the test results demonstrate that EM25 - glute toning device meet the requirements of its pre-defined acceptance criteria and intended uses.

5.9 Clinical Testing

No clinical test data was used to support the decision of safety and effectiveness.

5.10 Substantial Equivalence Determination

The EM25 - glute toning device is substantially equivalent in intended use, design, technology/principles of operation and performance to the cleared Buttock Muscle Stimulator, model: WL-2413E (K123075). Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Comparison of Significant device features:

	Proposed Device	Predicate Device
Item	EM25 - glute toning device	Buttock Muscle Stimulator
Model	EM25	WL-2413E
Manufacturer	Hivox Biotek, Inc.	Well-Life Healthcare Limited.
Intended Use	The EM25 - glute toning device is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrodes for the purpose of improvement of muscle tone of the buttocks muscles.	The Bullock Muscle Stimulator, model WL-2413E, is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrode for the purpose of improvement of muscle tone of the buttocks muscles.
Prescription or OTC	OTC	OTC
Regulation Number	890.5850	890.5850
Product Code	NGX	NGX
Electrode Used	K131720, HIVOX self-adhesive electrode gel pads	K082065, SiliconPad Electrode (7.0cm diameter)

Comparison of Basic Unit Characteristics:

		Proposed Device	Predicate Device
510(k) Number		K143737	K123075
Item		EM25 - glute toning device	Buttock Muscle Stimulator
Model		EM25	WL-2413E
Manufacturer		Hivox Biotek, Inc.	Well-Life Healthcare Limited.
Power Sources		1.5V x2 (AAA side) (Alkaline type ONLY)	1.5V x3 (AAA Size)
-Method of Line current Isolation		Type BF	Type BF
-Patient Leakage Current		—	—
Average DC current through electrodes when device is on but no pulses are being applied (μA)		N/A	N/A
Number of Output Modes		1	4
Number of output Channels:	Synchronous or Alternating?	Not applicable (one channel)	Synchronous
	Method of Channel Isolation?	Not applicable (one channel)	Output Coil
Regulated Current or Regulated Voltage?		Voltage	Voltage
Software/Firmware/ Microprocessor control?		Yes	Yes
Automatic Overload Trip?		No	No
Automatic No-Load Trip?		No	Yes
Automatic Shut Off?		Yes	Yes
User Override control?		Yes	No
Indicator	On/Off Status?	No, alerted by sound	Yes

Display:	Low Battery?	No, alerted by sound	Yes
	Voltage /Current Level?	No, alerted by sound	Yes
Timer Range (Minutes)		20	20-40
Compliance with Voluntary Standards?		IEC60601-2-10	IEC60601-2-10
Compliance with 21 CFR 898?		YES	Yes
Weight (g) including battery		133	80
Dimensions [W x H x D] (mm)		429 X 125 X 21	64 X 90 X 20
Housing Materials and construction		Silicone & ABS	ABS

Comparison of Output Specifications:

	Proposed Device	Predicate Device
Item	EM25 - glute toning device	Buttock Muscle Stimulator
Model	EM25	WL-2413E
Waveform (e.g., pulsed monophasic, biphasic)	Symmetrical Biphasic	Biphasic
Shape	Butterfly shaped	Retangular
Maximum Output Voltage (volts) - (+/- 20%)	64.8V @ 500Ω	40.8V @ 500Ω
	120V @ 2kΩ	70.0V @ 2kΩ
	132V @ 10kΩ	106.0V @ 10kΩ
Maximum Output Current (mA) - (+/-20%)	129.6mA @ 500Ω	8l.6mA @ 500Ω
	60mA @ 2kΩ	35.0mA @ 2kΩ
	13.2mA @ 10kΩ	10.6mA @ 10kΩ
Duration of primary phase (μsec)	400 fixed	300 Max
Pulse Duration (μsec)	400 fixed	720 Max
Pulse length	400 μs	unknown

Pulse Frequency (Hz)		4-50	70 Max
Atmospheric pressure operation		700-1060 hPa	unknown
For multiphasic waveforms only:	Symmetrical phases?	Yes	Yes
	Phase Duration	N/A	N/A
Net charge (μC)		0	0
Method of achieving zero net charge for net charge/pulse		Biphasic symmetric wave for each pulse	Biphasic symmetric wave for each pulse
Max. phase charge		50 μC	24 μC
Max. current Density		1.1549mA/cm²/500Ω	0.0997 mA/ cm²
Max. Power Density		0.0748Watts/cm²/500Ω	0.00399 Watts/ cm²
Max. Average current(RMSA)	500Ω	129.6mA	38.644mA
	2KΩ	60mA	16.907 mA
	10Ω	13.2mA	5.120 mA
Burst Mode		YES	Yes
Pulse per burst		50	Same for each program
Burst per second		18	Same for each program
Burst duration		400μs	Same for each program
Duty Cycle		7200	Same for each program

5.11 <u>Summary for the comparison</u>

The EM25 - glute toning device is substantially equivalent in intended use, design, technology/principles of operation and performance to the predicate device, Buttock Muscle Stimulator, model: WL-2413E (K123075). The proposed device has tested on safety and performance tests and the results were complied with the test requests. Although there are some differences in the output parameters between proposed device and predicate device, the differences did not raise any problems of safety or effectiveness.

5.12 Conclusion

After analyzing bench tests, safety testing data, it can be concluded that the EM25 - glute toning device is substantially equivalent to the predicate device.